

Effects of brief mindfulness-based cognitive behavioural therapy on health-related quality of life and sense of coherence in atrial fibrillation patients

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Abstract

Background: The aim of this study was to evaluate the effects of a brief dyadic cognitive behavioural therapy (CBT) programme on the health-related quality of life (HRQoL), as well as the sense of coherence in atrial fibrillation patients, up to 12 months post atrial fibrillation.

Methods: A longitudinal randomised controlled trial with a pre and 12-month post-test recruitment of 163 persons and their spouses, at a county hospital in southern Sweden. In all, 104 persons were randomly assigned to either a CBT ($n=56$) or a treatment as usual (TAU) group ($n=55$). The primary outcome was changes in the HRQoL (Euroqol questionnaire; EQ-5D), and the secondary outcomes were changes in psychological distress (hospital anxiety and depression scale; HADS) and sense of coherence (sense of coherence scale; SOC-13).

Results: At the 12-month follow-up, the CBT group experienced a higher HRQoL than the TAU group (mean changes in the CBT group 0.062 vs. mean changes in the TAU group -0.015 ; $P=0.02$). The sense of coherence improved in the CBT group after the 12-month follow-up, compared to the TAU group (mean changes in the CBT group 0.062 vs. mean changes in the TAU group -0.16 ; $P=0.04$). The association between the intervention effect and the HRQoL was totally mediated by the sense of coherence ($z=2.07$, $P=0.04$).

Conclusions: A dyadic mindfulness-based CBT programme improved HRQoL and reduced psychological distress up to 12 months post atrial fibrillation. The sense of coherence strongly mediated the HRQoL; consequently, the sense of coherence is an important determinant to consider when designing programmes for atrial fibrillation patients.

Keywords

Cognitive behavioural therapy, health-related quality of life, intervention, randomised controlled trial, sense of coherence, spouse, atrial fibrillation

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Introduction

Atrial fibrillation (AF) is the most common form of arrhythmia¹ impacting health-related quality of life (HRQoL). AF patients suffer from psychological distress, which also makes it difficult to cope with AF.^{2,3} Thus, this condition may impair the patient's sense of coherence (SOC)⁴ in terms of life complicating problems, across all health dimensions.^{5,6} Systematic reviews of worldwide population-based studies estimate that the number of persons with AF exceeds 33.5 million⁷ and that the prevalence of AF across all studies is 2.3%, which increases to 4.4% in those aged 65 years and

older.⁸ AF causes fatigue and worry, which together create a barrier to living life to the fullest, as those who

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suffer from it give up undertakings.² Those affected constantly need to find short-term and long-term strategies to prevent AF from reoccurring.^{2,9} A high SOC provides patients with a better position from which to understand, confront and deal with problems, as in a cardiac context, leading to a better HRQoL.^{10,11} SOC is a central concept consisting of the components comprehensibility, manageability and meaningfulness. SOC develops until the age of 30 years, after which it stabilises and remains constant throughout the rest of life.¹⁰ At this time, studies describing the effect of the SOC on the HRQoL after a cognitive behavioural therapy (CBT) programme are lacking. A large and growing body of literature have demonstrated that CBT programmes can be a useful approach for the treatment of psychological problems among cardiac patients.^{12–14} Mindfulness-based CBT was originally developed by Segal and colleagues to gain freedom from reactions to thoughts, feelings and events by patients.^{15,16} In this treatment, patients are encouraged to accept their thoughts without judgement. Two meta-analyses of randomised controlled trials (RCTs) indicated that mindfulness-based CBT was effective in reducing mental health problems (e.g. anxiety, depression and psychological distress) in adults with chronic somatic diseases.^{17,18} Furthermore, mindfulness-based CBT was found to be effective in improving psychological and physiological outcomes in patients with cerebrovascular disease.¹⁹ Mindfulness-based CBT has also been used in cardiac rehabilitation in daily clinical practice, to increase patients' awareness of their thoughts and activities, especially during their rehabilitation process.²⁰ One of the techniques that boosts the mindfulness-based CBT response in clinical populations is spousal involvement.²¹ Living together with a spouse when suffering from AF affects not just the patient's health dimensions and HRQoL, but that of the patient's spouse as well.^{2,22,23} Both AF patients and their spouses experience uncertainty, anxiety and depression, i.e. psychological distress, which are associated with deterioration in HRQoL as a result of AF.^{1,3,24} Depression in AF patients is also associated with lowered spirits in spouses and vice versa.^{24,25} Accordingly, as AF is unpredictable, it brings life-changing consequences that affect the dyadic health dimensions, with regard to both HRQoL and SOC. Although there are a few studies that focus on dyads in AF patients,²⁵ there are no results for non-medical pharmacological interventions, i.e. a CBT programme aimed at AF patients and/or their spouses.^{3,26–28} Moreover, when evaluating studies encompassing a broader cardiac context, there are few such studies, and there is no consensus regarding the beneficial effects of CBT on HRQoL.²⁹ Accordingly, the aim of this study was to evaluate the effects of a brief dyadic CBT programme on HRQoL as well as SOC in AF patients up to 12 months post AF.

Methods

Study design and setting

The study was a prospective, longitudinal single-blind RCT with a pre-test and a 12-month post-test recruitment of patients and spouses, between September 2011 and December 2015, at the Department of Cardiac Diseases, at a county hospital in southern Sweden. In all, 163 consecutive AF patients were enrolled prior to hospital discharge. The study was registered with the ClinicalTrials.gov registry (NCT02226575) and approved by the regional ethical review board at Linköping University (ref. no. M145-09). The CONSORT statement was used as a checklist to ensure the quality of the RCT.

Participants, sample size and randomisation process

Consecutive AF patients and their spouses enrolled in the study after receiving both oral and written information, and having given written consent prior to inclusion. The inclusion criteria for participating were: (a) age 18 years or above; (b) AF diagnosis, and (c) accompanied by a spouse. Patients were excluded if they had severe complications due to their current disease, unstable coronary artery disease, sepsis or other severe infection, AF early after thoracic surgery, acute pulmonary embolism, known hyperthyroidism, malignant disease with expected survival of less than one year, dementia, residence outside the hospital's catchment area, current participation in another study and difficulties with the Swedish language preventing them from completing questionnaires. The sample size was calculated by using G*Power, which provided a sample size of 45 per group, when considering 90% power of detecting a moderate difference between the two groups of care for HRQoL, with a significance level of 5% (alpha error), and allowing for a possible 20% attrition.³⁰ A 1:1 randomisation was performed by an independent statistician, with a computer-generated sequence of random numbers. Due to the nature of the study design, it was not possible to blind the AF patients or spouses to the study intervention. However, the statistician and outcome assessors were blinded to the study groups. In all, 163 AF patients and their spouses were invited to take part, while 122 fulfilled the criteria (Figure 1) and 104 were randomly assigned to either the CBT ($n=56$) or the treatment as usual (TAU) groups ($n=55$). Fifteen patients (26.8%) from the CBT group did not participate in the sessions as they were not accompanied by their spouses. In addition, 18 AF patients (32.7%) from the TAU group were not available at follow-up. The mean age of the AF patients was 66.70 years (standard deviation (SD) 9.4). Of the 104 patients, 57 (54.8%) were women, 33 (31.7%) were employed and 38 (36.5%) had completed a high school education. There

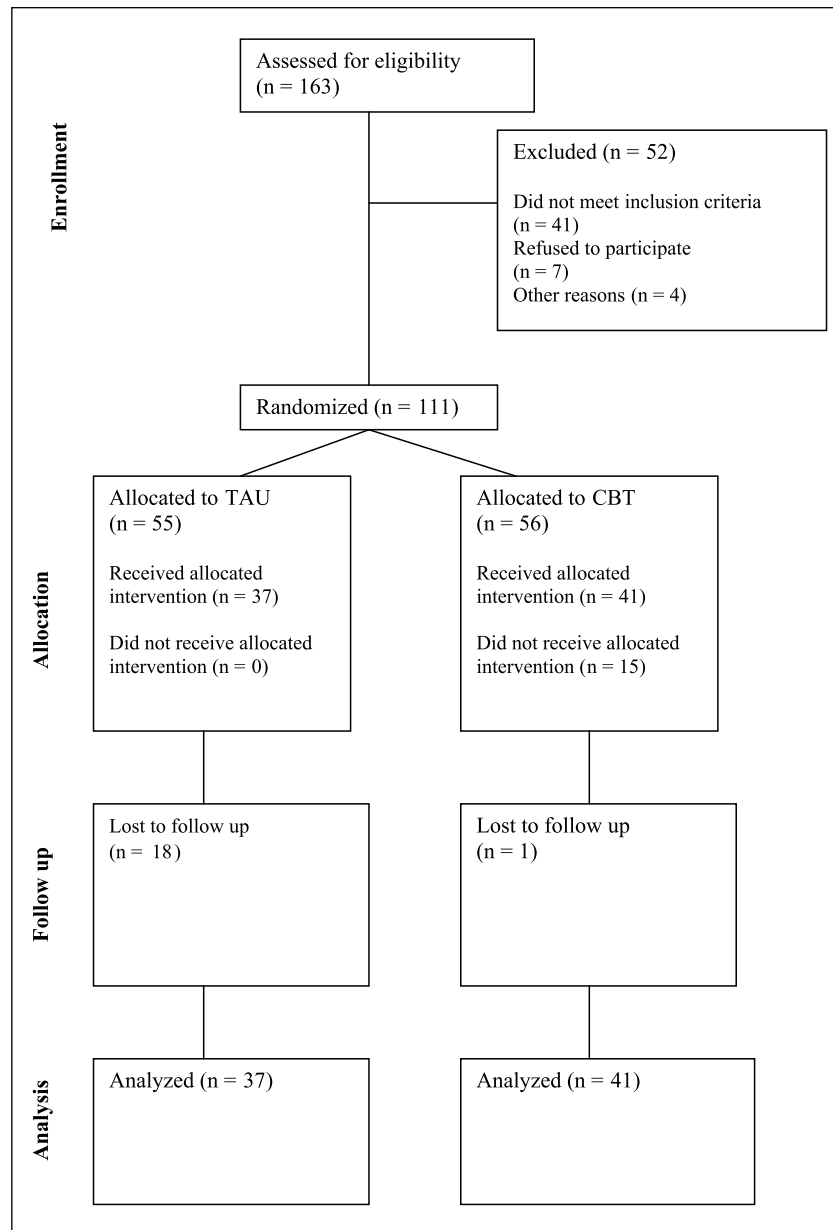


Figure 1. Flow chart of inclusion and follow-up in the study.

was no significant difference between the CBT and TAU groups in terms of sociodemographics and type of AF (Table 1).

Interventions

Treatment as usual. Patients in both groups received standard treatment (i.e. TAU) at the hospital. The diagnosis was based on a 12-lead ECG and an examination and information from a hospital physician. TAU as ‘optimal treatment’ might require 24-hour Holter ECG monitoring. The number of episodes, duration of the episodes and the severity of symptoms determined the appropriate medication.

Patients were prescribed anticoagulants according to guidelines, warfarin or a non-vitamin K antagonist oral anticoagulant based on CHA2DS2-Vasc scores.^{31,32} When discharged from hospital, AF patients were encouraged to reduce the risk of new AF episodes by exercising regularly, refraining from smoking or using snuff, not exceeding a moderate intake of alcohol and coffee, and avoiding psychological distress, in accordance with provided guidelines.³³ If the AF episodes occurred occasionally, without body–mind impact, no measures were needed; but if the AF episodes became more frequent or produced symptoms, such as shortness of breath and chest pain, they were advised to contact healthcare. Paroxysmal AF is

Table 1. Sociodemographic and clinical characteristics of the atrial fibrillation patients included in the study.

	TAU	CBT	P-value
Age	66.89 (11.02)	67.54 (8.62)	
Gender			0.972
Male	20 (54.1%)	22 (53.7%)	
Female	17 (45.9%)	19 (46.3%)	
Work status			0.587
Employed	12 (34.2%)	11 (26.8%)	
Unemployed	25 (67.6%)	30 (73.2%)	
Education			0.478
Less than elementary school	4 (10.8%)	3 (7.3%)	
Elementary school	7 (18.9%)	14 (34.1%)	
High school	14 (37.8%)	12 (29.3%)	
College/university	12 (32.4%)	12 (29.3%)	
Diagnosis			0.115
First episode	5 (13.5%)	11 (26.8%)	
Paroxysmal AF/AFL	19 (51.4%)	16 (39.0%)	
Persistent AF/AFL	8 (21.6%)	13 (31.7%)	
Permanent AF/AFL	5 (13.5%)	1 (2.4%)	

CBT: cognitive behavioural therapy group; n=37; TAU: treatment as usual group; n=41; AF: atrial fibrillation; AFL: atrial flutter.

commonly self-terminating within 48 hours. However, if a patient's AF episode persisted longer than 24 hours, they were advised to seek healthcare for diagnostics and management of the AF.³³ The patients in the TAU group did not receive any CBT during the intervention period.

The CBT programme. The CBT programme consisted of three 2.5-hour group sessions over a period of 9 weeks, with four to six AF patients, including spouses. The sessions were conducted by three therapists (a cardiac nurse, a cardiologist and an educationalist), who were trained by an educator with certification from HeartMath Scandinavia in CBT, with a focus on mindfulness practices.³⁴ HeartMath Scandinavia provides training sessions in mindfulness for healthcare professionals. In these sessions, participants were trained to be aware of their breathing.³⁵ Moreover, heart rate variability biofeedback was demonstrated during these training sessions.³⁶ HeartMath is a standardised and easy-to-learn stress reduction programme for both patients and the general population.³⁷ HeartMath comprises a series of self-regulation techniques that facilitate, through the regulation of emotions and behaviours, the achievement of top psychological coherence. This intervention has been shown to be successful in reducing stress among police officers.³⁸

A detailed tutorial manual was developed for the therapists, which outlined the contents of how to teach the exercises to the patients and their spouses, both at the meetings and at home (Figure 2). In brief, patients in the first session tried to identify and stop unpleasant feelings and negative thoughts that led to cognitive distortions. Positive

psychology was focused upon in the second session. These two sessions can help patients to build and strengthen their personal resilience. In the final session the patients were taught to work smarter rather than harder. Patients also experienced the results of positive thinking on their hearts and brains.

A corresponding participant manual was provided to each patient that contained the educational information, as well as instructions on mindfulness practice, to be followed at home. Each subsequent session included at least a 15–20-minute mindfulness practice that targeted the different foci, e.g. heart focus, heart breathing (Figure 2) guided by the therapist. This was followed by an enquiry about the participants' experiences during practice, as well as encouragement to practice at home on a daily basis.

Primary and secondary outcomes

The primary outcome was a change in HRQoL, from pre to post-treatment, as assessed by the Euroqol questionnaire (EQ-5D).³⁹ The secondary outcomes were changes in psychological distress and SOC, as assessed by the hospital anxiety and depression scale (HADS) and the sense of coherence scale (SOC-13), respectively.^{40,41}

Data collection

Sociodemographic and clinical data. AF patients and spouses answered questions about age, gender, education and employment. Clinical data were collected through medical record reviews, e.g. clinical diagnosis and time since diagnosis.

Euroqol questionnaire. The EQ-5D has five self-reported items assessing mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The response items are rated on three levels (no problems, moderate problems, severe problems). The weights for the EQ-5D preference-based index used were obtained from the Swedish general population, using the time trade-off method.³⁹

Hospital anxiety and depression scale. The HADS has 14 self-reported items assessing psychological distress, with seven items forming an anxiety subscale and another seven forming a depression subscale. Each item is rated on a four-point Likert-type scale, ranging from 0 to 3, with 3 indicating a higher symptom frequency. Scores of anxiety and depression subscales ranged from 0 to 21, where 0–3 is normal range, 4–7 is subclinical, 8–10 is mild, 11–14 is moderate and 15–21 is severe. The Swedish HADS version shows good internal consistency and factor structure.⁴¹

Sense of coherence scale. The SOC-13 has 13 self-reported items assessing the concept of SOC. The items comprise three subscales: comprehensibility (five items), manageability (four items) and meaningfulness (four items). Each

Session	Aim	Procedure	Material	Goal
Meeting I	Introducing self-awareness <ul style="list-style-type: none"> • Physically • Psychologically • Mentally 	Step 1. Heart focus: by controlling thoughts to the heart Step 2. Heart breathing: by inhaling and exhaling, going through the heart, feeling neutral, the discomfort decreases	HeartMath Scandinavia	Stopping unpleasant feelings and negative thoughts
Meeting II	Training physical, psychological and mental functions <ul style="list-style-type: none"> • Experience of pleasant feelings • Influencing energy and balance 	Repeat exercises from Meeting 1 Step 3. Positive feeling: of something that is appreciated in everyday life by spreading it from the heart into the body. Step 4. Focus: on a pleasant feeling in the environment, such as caring for a loved one	HeartMath Scandinavia	Maintaining pleasant feelings for at least 6 minutes
Meeting III	Evaluating what gives energy and positive feelings, and influences both the heart and brain	Repeat exercises from Meeting 2 <i>Practicing positive feelings;</i> together in a group on the basis of heart focus, heart breathing, positive emotion and focused feelings	HeartMath Scandinavia	Working with environments that are to be affected

Figure 2. Structure and content of the brief patient–spouse cognitive behavioural therapy programme.

item response is rated on a 7-point Likert-type scale from 1 ('very often') to 7 ('very seldom' or 'never'). All items can be added together to give a total score ranging from 13 (lowest) to 91 (highest). The Swedish version of the SOC-13 has been shown to be valid and reliable.⁴⁰

Data analysis

All analyses were performed using IBM SPSS Statistics version 21 software (IBM, Armonk, NY, USA). Sociodemographic and clinical characteristics were compared across the groups using a chi-square test or Fisher's exact test, when appropriate for categorical data, and the Student's *t*-test for continuous variables. Statistical analyses were performed on an intention-to-treat basis. An analysis of covariance was used to estimate the between-group differences and adjusted for pre-test values: age, gender, education and type of AF. Age, gender, education and type of AF were considered as covariates, as several studies have shown considerable associations between these covariates and HRQoL, as well as psychological distress in a cardiac context.^{42–44} Mean change scores were calculated (difference between pre-test and post-test scores of the participants) for each primary and secondary outcome. A standardised response mean (SRM: mean change scores divided by a pooled SD) was used to estimate the effect size of the intervention for each outcome. Based on Cohen's classification of effect sizes, SRM less than 0.2 is trivial, 0.2–0.5 is small, 0.5–0.8 is medium and 0.8 or greater is large. In addition, the mean change scores were categorised into two groups based on the mean changes:

improved (positive mean change scores) and declined (negative mean change scores). Series of logistic regression analyses were conducted, adjusting for age, gender, education and type of AF, to estimate the effect of the intervention on improving or declining patients' outcomes.

Moreover, a series of multiple linear regression analyses were carried out to test whether the CBT worked by way of the hypothesised mechanism (i.e. SOC). Four steps of the Baron and Kenny approach were used to test the mediation variable.⁴⁵ In the first step, an independent variable (i.e. the CBT programme) was tested for correlation with the dependent variable (HRQoL: EQ-5D time 2, i.e. path *c*). The second step tested if the independent variable (i.e. the CBT programme) correlated with the mediator (i.e. SOC time 2, path *a*). The third step tested whether the mediator correlated with the dependent variable (i.e. path *b*). In the final step, both the independent variables (i.e. the CBT programme) and the mediator (i.e. SOC time 2) were tested for correlation with the EQ-5D as the dependent variable (i.e. path *c'*). Complete (or total) mediations are present if the results of the three steps are significant; however, the independent variables were not significantly correlated with the dependent variable at the fourth step. Partial mediation occurs if this correlation decreases. These analyses were followed by use of the Sobel test⁴² to determine the indirect effects of the intervention on HRQoL through the potential mediator (i.e. SOC time 2). The mediating effect is significant at the level of 0.05, if the Sobel test values are greater than 1.96. The bias-corrected Bootstrap was used to calculate the indirect estimate of intention on the HRQoL

Table 2. Descriptive statistics for all outcome measures by condition and time of atrial fibrillation patients.

	Condition	Pre-test	12 months post-test	Mean change from baseline to month 12 (SD)	SRM	P-value
EQ-5D*	TAU	0.75 (0.21)	0.74 (0.22)	-0.01 (0.21)	-0.05	0.03
	CBT	0.72 (0.20)	0.79 (0.18)	0.07 (0.19)	0.37	
Anxiety	TAU	5.64 (4.08)	5.76 (4.19)	0.12 (4.13)	0.03	0.40
	CBT	5.07 (3.43)	4.85 (3.78)	-0.22 (3.60)	-0.06	
Depression*	TAU	4.11 (3.09)	4.16 (2.97)	0.05 (3.03)	0.02	0.04
	CBT	3.92 (2.82)	3.15 (2.86)	-0.77 (2.84)	-0.27	
SOC-13	TAU	25.70 (5.29)	26.21 (5.10)	0.51 (5.19)	0.10	0.02
comprehensibility*	CBT	27.17 (5.39)	29.10 (4.03)	1.93 (4.71)	0.41	
SOC-13	TAU	22.00 (3.87)	21.40 (3.76)	-0.6 (3.81)	-0.16	0.10
Manageability	CBT	22.80 (3.22)	23.05 (3.81)	0.25 (3.51)	0.07	
SOC-13	TAU	22.54 (3.39)	22.46 (3.17)	-0.08 (3.28)	-0.02	0.22
Meaningfulness	CBT	23.34 (3.89)	23.90 (3.19)	0.56 (3.54)	0.16	
SOC-13*	TAU	70.24 (11.17)	70.08 (11.16)	-0.16 (11.16)	0.01	0.04
Total	CBT	73.31 (11.07)	76.15 (8.73)	2.84 (9.9)	0.29	

CBT: cognitive behavioural therapy group: $n=37$; TAU: treatment as usual group: $n=41$; SRM: standardised response mean.

* $P<0.05$, Adjusting for multiple comparisons using the Benjamini–Hochberg adjustment.

Note: All results were adjusted for age, gender, education and type of atrial fibrillation.

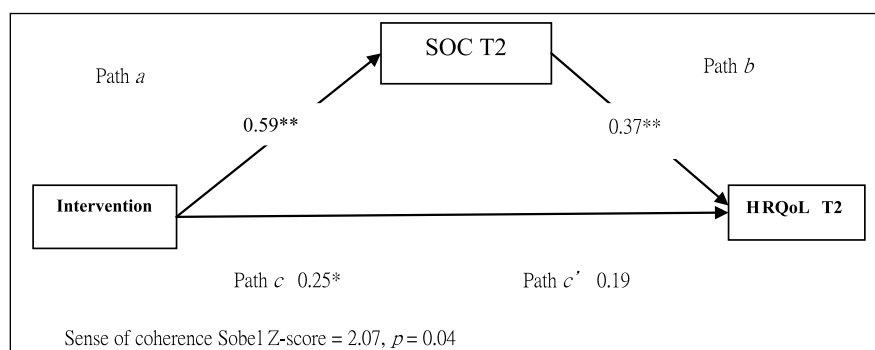


Figure 3. Three-variable framework of the mediation effect. In this model, the cognitive behavioural therapy (intervention) is assumed to have both a direct and indirect sense of coherence (SOC) path to the outcome of health-related quality-of-life (HRQoL). Path a is the effect of the independent variable (cognitive behavioural therapy (CBT) intervention) on the mediator (SOC) and path b is the effect of the mediators on the outcome variable (change in HRQoL). Path c' is the direct effect of the independent variable (CBT intervention) on the outcome variable (HRQoL). The total effect (c) of the CBT intervention on the HRQoL is the sum of the direct effect (c') and the total indirect effect (ab).

with 1000 Bootstrap samples and a 95% confidence interval. A P value of less than 0.05 (two-tailed) was considered significant for all statistical tests. All P values were adjusted for multiple comparisons using the Benjamini and Hochberg adjustment method⁴⁶ to control for the false discovery rate in multiple testing.

Results

The mean scores of the CBT and TAU groups on HRQoL, psychological distress and SOC are presented in Table 2. Analysis of covariance showed that the CBT group had increased HRQoL compared to the TAU group ($f(103.1) = 6.18$; $P=0.02$). The CBT group also experienced a reduction in depression ($f(103.1) = 4.58$; $P=0.04$). The SOC

improved in the CBT group after the 12-month follow-up, compared to those in the TAU group ($f(103.1) = 4.15$, $P=0.04$). The logistic regression confirmed the significant influence of the CBT on the HRQoL (adjusted odds ratio (AOR) 2.97, 95% confidence interval (CI) 1.10–8.09), SOC (AOR 2.78, 95% CI 1.08–7.17) and depression (AOR 0.31, 95% CI 0.10–0.91). Moreover, the association between the intervention effect and the HRQoL was totally mediated by the SOC (Figure 3). The Sobel test further demonstrated that approximately 14% of the variation was mediated by the SOC ($z=2.07$, $P<0.05$, 95% bootstrapped CI 0.05–0.54). In addition to the total score for SOC, comprehensibility was also tested to determine if it could play a mediating role between the intervention effect and the HRQoL. The direct effect was not significant ($\beta=0.07$,

standard error (SE) 0.05, $P > 0.05$) when controlling for the mediation variable (i.e. SOC), and comprehensibility was observed as a total mediator between the intervention effect and the HRQoL ($z = 2.12$, $P < 0.05$, 95% bootstrapped CI 0.02–0.09).

Discussion

Methodological considerations

To some extent, this study demonstrates that receiving brief dyadic mindfulness-based CBT influenced the HRQoL in patients and their spouses. However, few studies have shown beneficial effects of SOC on HRQoL^{47,48} and no study has demonstrated any mediating role of SOC in a randomised trial. An RCT is the most powerful and straightforward method of establishing a cause and effect conclusion. Treatment mediators identify possible mechanisms by which an independent variable influences an outcome variable. The fact that all mechanisms are mediators, but not all mediators are mechanisms, highlights the importance of testing mediation in an empirical setting. A given mediator will then be a mechanism if it is found to be effective in an original RCT study. Understanding the role of a SOC as a mechanism for improving HRQoL facilitates the development of treatment modalities for AF patients. In addition, this was the first time a study evaluated spousal involvement in improving HRQoL in AF patients. It is documented that spouses of individuals with disabilities may experience similar psychological problems in the patient–spouse dyad.⁴⁹ Therefore, a psychological intervention targeting both patients and spouses offers greater promise. However, we did not evaluate changes over time for psychological distress and HRQoL in spouses. Thus future studies should focus on dyadic evaluations of the patient–spouse interaction for HRQoL. While the efficacy of the CBT programme was shown to be maintained in the long-term, by means of a 12-month follow-up, it was not possible to differentiate between long-term, medium-term and short-term therapy. In addition, the generalisability of our results is limited by the fact that the efficacy of the CBT programme was evaluated at a single centre with no racial/ethnic differences. In this study, the risk factors of AF (e.g. bleeding, abnormal liver function and diabetes mellitus, etc.) were not assessed. Future studies should include the role that these risk factors play in deteriorating patients' HRQoL. Despite the therapists being highly experienced and having received a standard education, we did not evaluate the fidelity of the treatment or sessions, which we state to be a limitation. More than a quarter of AF patients in the CBT group did not receive the allocated intervention due to a spouse not being present. Finally, AF patients in the CBT group participated in several sessions, totalling 8 hours, whereas AF patients in the TAU group only spent minutes on

medication and lifestyle modifications and lack of attention control.

Results-based considerations

A significant finding was that AF patients benefitted from a brief dyadic mindfulness-based programme as compared to TAU, in terms of improved HRQoL and decreased psychological distress, over a duration of 12 months. Another significant finding was the association between the SOC and the HRQoL, which underscores the impact the SOC has on the HRQoL. These substantial findings provide evidence that this CBT programme is an effective tool in the cardiac care of AF patients for the management of psychological distress. The ease with which the CBT programme is handled in daily clinical practice provides good opportunities with AF patients, as well as spouses and healthcare professionals. Therefore, future evaluations of the effects of CBT programmes on AF patients could become increasingly interesting, as studies concerning patients with myocardial infarction show improvements in the survival rate exceeding 10%.¹⁴ However, as the SOC strongly mediated the HRQoL, it is also a significant, generalised, resistance resource when coping with a stressful life events such as AF. The CBT programme was designed on a dyadic basis, i.e. dyadic interaction, but its impact on spouses is described elsewhere.²⁴ Although there is currently no study that evaluates the SOC of a CBT programme on the HRQoL mediating effect on AF patients, in a broader cardiac context, the SOC has shown a mediating effect on psychological distress.⁵⁰ Likewise, in line with our longitudinal study design, but in a breast cancer context, the SOC was a mediator of the HRQoL.⁵¹ Accordingly, the mediating effect of SOC on HRQoL in the cardiac context appears to be crucial in understanding how the SOC gains as an inner resource, such as a promotive factor in managing a stressful life event such as AF. The SOC is an important determinant that should be taken into account when designing programmes for AF patients, as it has an impact on psychological distress and significant, albeit indirect, effects on the HRQoL.

Conclusions

A brief dyadic mindfulness-based CBT programme, when compared with TAU, showed improved HRQoL and decreased psychological distress up to 12 months post AF. The SOC also strongly mediated the HRQoL, consequently the SOC is an important determinant to consider when designing programmes for AF patients. The results highlight the importance of spouses accompanying patients during the cardiac rehabilitation process. Therefore, patients and spouses are in need of being viewed as a dyad and not only as individuals. The clinical implication of the CBT programme is its usefulness, user-friendliness and

ease of implementation in daily clinical practice. Clinicians can use the brief CBT manual and worksheet, as well as the homework assignments and information materials with AF patients and their spouses. Further research is warranted to evaluate the effects on HRQoL and SOC in a long-term follow-up and its associated effects on the spouses of patients who have participated in a brief dyadic mindfulness-based CBT programme.

Implications for practice

- The HeartMath cognitive behavioural therapy programme is an easy to use tool on how to handle and reduce psychological distress in both patients and spouses.
- It is easy to implement in daily practice.
- Currently, there are no good care routines for handling atrial fibrillation in patients and spouses, which is why more guidance is needed by healthcare professionals.

Clear messages for cardiovascular nurses

- Patients and spouses are in need of being viewed as a couple and not as individuals only.
- Through knowledge regarding atrial fibrillation in acute and long-term situations (up to 12 months), sense of coherence mediated strongly on health-related quality of life, and sense of coherence is consequently an important determinant to be taken into consideration when designing programmes for atrial fibrillation patients.
- The HeartMath stress reduction programme can be added to routine treatment during cardiac rehabilitation.

Declaration of conflicting interests

None declared.

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Trial registration

NCT02226575

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